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10/057,610	01/25/2002	Richard Wisniewski	2035750	3124

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EXAMINER

FORD, JOHN K

ART UNIT	PAPER NUMBER
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 10/057,610
Filing Date: January 25, 2002
Appellant(s): WISNIEWSKI et al.

Brett M. Hutton
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 14, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

This is one of four related appeals that the Board is urged to take up simultaneously. These four appealed applications are: SN 08/895,936, SN 10/057,610, SN 09/881,909 and SN 10/056,237.

(3) *Status of Claims*

The statement of the status of the claims at the time of the final office action is correctly reproduced at the bottom of page 3 of the Brief.

(4) *Status of Amendments After Final*

The statement of the status of the claims contained in the Brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is deficient because it does not reference any portion of the specification nor make any reference to any drawing or reference numerals.

Figures 1 and 2 constitute the elected species and are described on page 15, paragraph 62 through page 19, paragraph 74 of the specification, which is incorporated here by reference.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Issue 3 is an issue that the Board of Appeals has no jurisdiction over. The P.T.O. does not decide such matters.

(7) *Grouping of Claims*

All of claims 1-5 and 20-29 stand or fall together. The Board should note that independent claim 1 is the broadest claim on appeal and the Examiner's comments will pertain primarily to that claim.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

"Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product,"
Richard Wisniewski and Vincent Wu, (both employed at Genentech). Proceedings of the
International Congress, Advanced Technologies for Manufacturing of Aseptic &
Terminally Sterilized Pharmaceuticals & Biopharmaceuticals, Basel, Switzerland, 17-19
February 1992, Convention Center Basel, pp 132-139.

"Studies of Heat Transfer From a Vertical Cylinder, With or Without Fins;
embedded in a Solid Phase Change Medium," B. Kalhori and S. Ramadhyani,
Transactions of the ASME, Journal of Heat Transfer, Vol. 107, February 1985 pp. 44-
51.

3,318,105	Burroughs et al.	5/1967
2,129,572	Finnegan	9/1938
2,114,642	West	4/1938

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5 and 20-29 are rejected under 35 U.S.C. 112, second paragraph. This rejection is set forth in a prior Office Action, mailed on 02/24/2004, beginning on page 11.

Claims 1-5 and 20-29 are rejected under 35 U.S.C. 103(a). This rejection is set forth in a prior Office Action, mailed on 02/24/2004, beginning on page 15.

(11) Response to Argument

Appellant's arguments begin on page 5 of the Brief and they are addressed here in the same order presented there:

1: "Biopharmaceutical Product"

In view of the explanation found on the pages 5-9 of the Brief, this rejection is withdrawn. Appellant has explained clearly for the first time on page 7 of the brief, what the examiner perceived to be an inconsistency between the specification with regard to "buffers" and the definition offer by declarants Burman, Lawlis and Vetterlein.

2.a. Alleged improper combinations of references

Notwithstanding that the term biopharmaceutical is definite, the examiner is not persuaded by the argument that orange juice, milk, water and comestibles do not exhibit

some of the same processing concerns as biopharmaceutical products. Other than opinion evidence, there doesn't appear to be any scientific evidence that this statement by Appellants is valid. In the course of prosecution appellants have submitted many prior art references for consideration, by the various examiners involved, related to freezing of food products that are not biopharmaceuticals. It is submitted that if this were unrelated art, as Appellants now contend, Appellants would not have produced it for consideration during prosecution. Moreover much of this prior art related to freezing of food products appears in the Appendices of the 1996 Wisniewski and Wu prior art, ample evidence that Appellants perceived food freezing prior art to be relevant to their invention, before the taking of this Appeal. As well, much of the prior art relied upon in the rejection discusses the problems of attaining uniform freezing of liquid food products (such as West 2,114,642) not unlike those that Appellants have encountered in processing biopharmaceuticals. Finally, it is well known in the heat transfer art that scientists routinely make heat transfer measurements in one material that can be extrapolated to other materials by known correlations, such as Reynolds number, Prandtl number and Nusselt number. There is in the record before the Board no objective evidence (e.g. test results etc.) demonstrating that the freezing of biopharmaceuticals is unique compared to other mixtures of organic cellular products such as orange juice and ice cream.

Appellant wants the examiner and the Board to ignore the prior art related to freezing and thawing in general and to pretend as if the art of freezing biopharmaceuticals is so unrelated to freezing and thawing of other liquid solutions as to

be not combinable. No evidence is offered to support this proposition, which is largely self-serving at its core. Appellant here did not invent the freeze tank for biopharmaceuticals. It was invented long before (in 1992) and is now in the public domain and also apparently the intellectual property of Genentech. All Appellant has done its to make an obvious modification of the prior art by substituting a superior centrally mounted heat exchange structure such as shown by Kalhori and Ramadhyani for that the centrally mounted heat exchange structure disclosed in 1992 Wisniewski and Wu prior art.

i. 1992 Wisniewski and Wu publication

Appellants make a whole series of self-serving statements about this prior art (including that the fins were small and thin and were designed only to ...). All of this is not found in the reference itself, but instead comes from Mr. Wisniewski's extremely spotty memory of this device. First of all, the fins are sizeable both as shown in the reference itself and in Mr. Wisniewski's first declaration Exhibits B-D. Thus the representations in the Brief are contradicted by the facts as represented in the first Wisniewski declaration. These assertions in the first Wisniewski declaration are contradicted, as have a number of assertions, by the second Wisniewski declaration. Mr. Wisniewski has remembered and then apparently forgotten so many important facts about the prior art, that the Examiner is unsure if any of the extrinsic evidence pertaining to Mr. Wisniewski's recollection of this prior art is reliable.

ii. 1986 Kalhori & Ramadhyani Article

While counsel doesn't appear to want to admit it, this 1986 article clearly discloses a centrally mounted heat exchange structure with fins, that is extremely efficient at both freezing and thawing the contents of the tank. Dovetailing with his first argument, counsel argues that the fact that paraffin, a phase change material with precise characteristics that make it ideal for heat transfer research, is used in the 1986 article, somehow make it completely irrelevant to processing biopharmaceuticals. On top of that counsel argues, without a single supporting bit of supporting evidence, that the 1986 and 1992 prior art "involve different principles of freezing." This is submitted to be nonsense. Phase change (freezing) is the same phenomena regardless of the composition of the liquid to be frozen. The fact that the 1992 prior art used finned tubes in the central structure teaches toward the 1985 prior art, not away from it.

Furthermore, the 1986 prior art is listed in the appendix (list of references) of the 1996 reprint of the 1992 article, making the argument that it is somehow irrelevant virtually hypocritical in nature. One of ordinary skill in the art would have certainly been motivated to look for devices that produce "superior heat transfer characteristics." The Examiner concludes in the final rejection:

"To have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 [to] improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal of the frozen mass would have been obvious to one of ordinary skill in the art."

Counsel does not present even a single argument against the three motivational reasons given by the Examiner.

The only argument counsel can muster is the fact that no human being (including Mr. Wisniewski, although he doesn't mention him by name) can accurately predict such results (meaning the actual temperatures in a partially frozen mass undergoing the freezing process in the tank, if the quote was taken in context). Purporting to have such ability only diminishes ones (meaning Mr. Wisniewski's, if the quote was taken in context) credibility.

This quote does not mean that those of ordinary skill in the art cannot make obvious improvements to known devices using well known, and in this case tested, alternative devices (namely the finned, centrally mounted, heat exchanger of the 1986 article).

The 1986 article states this as well when discussing the finned heat exchanger in the penultimate and last paragraph on page 50, to wit:

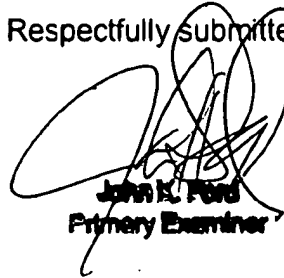
"However there is a significant enhancement in the total heat transfer due to the addition of fins. The augmentation of the rate of heat transfer is in accordance with expectation."

Thus, as the Board can now appreciate, the predictions of the temperatures distribution around the finned cylinder in a partially frozen mass undergoing freezing is a moving boundary problem in a complex geometry that is amenable only to numerical solution or experimental measurement (not to the type of mental analysis done by Mr. Wisniewski in Exhibits B-D of his first declaration), however the augmentation of the rate

of heat transfer by adding bigger fins is an entirely expected result (as evidenced by the aforementioned quote from the 1986 article) that counsel does not want to acknowledge.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



John K. Ford
Primary Examiner


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December 28, 2004

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